

**REMARKS**

Claims 1-8, 10, 12, 13 and 17-24 are pending. Claims 1-8, 10, 12, 13 and 17-24 have been rejected.

**The Information Disclosure Statement**

The Examiner alleges that the Information Disclosure Statement (“the Statement”) filed on March 14, 2005 fails to comply with the provisions of 37 C.F.R. §§1.97, 1.98 and MPEP §609. Specifically, the Examiner alleges that no documentation has been presented to substantiate the public sale of the claimed device. The Examiner further states that, *inter alia*, the date of submission of any missing elements will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement.

Applicants submit herewith a duplicate copy of the Statement, including PTO-1449 form, and copies of the following documents: (1) a print out from Arrow’s database, which indicates that the date of first sale was April 17, 2000; and (2) a March 8, 2000 Food and Drug Administration 510(k) Premarket Notification letter. Applicants assert that this submission now complies with the provisions of 37 C.F.R. §§1.97, 1.98 and MPEP §609.

**The Rejections under 35 U.S.C. §102(b)**

The Examiner has rejected claims 1-8, 10, 12, 13 and 17-24 under 35 U.S.C. §102(b) on a public use or sale of the invention. The Examiner stated that, to properly consider the patentability of the claimed invention under §102(b), applicants must provide documentation as to the public sale of the claimed invention. Accordingly, as stated above, applicants submit herewith a duplicate copy of the Statement, a copy of a print out from Arrow's database, which indicates that the date of first sale was April 17, 2000, and a copy of a March 8, 2000 Food and Drug Administration 510(k) Premarket Notification letter.

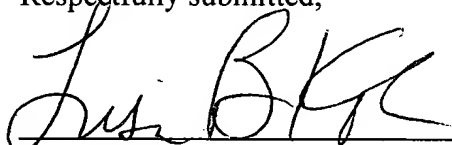
The instant application was filed on December 22, 2000. The date of the first sale of the claimed invention was April 17, 2000, well within the statutory one-year period prior to the filing date of the application. As such, applicants assert that claims 1-8, 10, 12, 13 and 17-24 are patentable under 35 U.S.C. §102(b). Accordingly, applicants request that the rejection under 35 U.S.C. §102(b) be withdrawn and the claims allowed.

**Conclusion**

Applicants believe that in light of the foregoing remarks, the claims are in condition for allowance, and accordingly, respectfully request withdrawal of the outstanding rejections. An allowance is earnestly sought. The Examiner is invited to telephone the undersigned if it would help in advancing the application to allowance.

August 17, 2005

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Lisa B. Kole", written over a horizontal line.

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